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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,392	FITA, FERNANDO BOUFFARD	
	Examiner	Art Unit	
	Jody L. Karol	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/16/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *25* is/are allowed.

6)☒ Claim(s) *1-5, 7-12, 14-15, 17, 19-20, 22, 24, and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 7/16/208. Claims 17 and 25-26 have been amended. Claims 6, 13, 16, 18, 21 and 23 were previously been cancelled. Thus, claims 1-5, 7-12, 14-15, 17, 19-20 are pending and currently under consideration.

A telephone call was made to Peter Scull on 1/15/2009 to discuss allowable subject matter and to request approval for an Examiner's amendment, but did not result in approval for said request.

WITHDRAWN REJECTIONS

1. In view of Applicant's amendment to the abstract and specification, the objection to the specification is herein withdrawn.

2. In view of Applicant's amendment to claim 17, the objection to claim 17 is herein withdrawn.

3. In view of Applicant's amendment to claim 25, the rejection of claim 25 under 35 U.S.C. 112, second paragraph for being indefinite for containing trademarks is herein withdrawn.

4. Applicant's Applicant's arguments regarding the rejection of claim 26 under 35 U.S.C. 103(a) as being unpatentable over Cassel (US 2002/0128285) and Samuels et al. (US 2002/0006435 A1) in view of Lutz et al. (US 5,750139) and Santana et al. (US 2003/0103955 A1) have been fully considered and are persuasive. Thus, said rejection has been withdrawn.

Response to Arguments

5. Applicant's arguments filed 7/16/2008 have been fully considered but they are not persuasive.

Applicants argue that the claimed topical anesthetic composition comprising the specific combination of anesthetics lidocaine, prilocaine, and tetracaine has new, different, and unpredictable advantages, purposes and effects such as decreased side effects. In response it is respectfully submitted that it is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the evidence presented is not reasonably commensurate in scope with the scope of the subject matter claimed. Only one specific formulation is provided as evidence, which does not provide basis upon which one can reasonably extrapolate and conclude that the unexpected results would be present in all the claimed compositions. For example, the formulation is limited to an amount of 1.5% (w/w) for each anesthetic, but several of the claims do not recite any specific amount of anesthetic. The formulation also contains many additional specific excipients that are not recited in the claimed formulations. It is unclear whether the presence of these excipients is critical/necessary to obtain the unexpected results. It is also noted that comparison between the EMLA cream and the composition of the instant invention is not a 1:1 comparison, and different variables seem to be tested at the same time. The EMLA cream contains 2.5% (w/w) each of lidocaine and prilocaine while the composition of the instant invention contains only 1.5% (w/w) each of lidocaine and prilocaine, the EMLA cream and the composition of the instant invention are applied at different times, the EMLA cream is applied with occlusion while the composition of the instant invention is not applied with occlusion, and the anesthetic efficacy and/or side effects are measured after different lengths of use (resulting from the difference in application times). To effectively demonstrate unexpected results, the variables (i.e. length of application time, amount of anesthetic components) governing the results need to be compared side by side, and tested one variable at a time. Furthermore, while Applicant's assert the presence of prilocaine stabilizes the tetracaine in the composition of the instant invention, the Applicant's data is entirely bereft of any

statement or evidence that would demonstrate tetracaine is stabilized by prilocaine. Lastly, the decrease in side effects of prilocaine is not seen as unexpected. In combining the three anesthetic components, at least an additive anesthetic effect is expected, and thus, less amounts of each anesthetic would be required to achieve the same effect as each of the components alone. A lesser amount of prilocaine (1.5% (w/w)) and the other anesthetics are present in the composition of the instant invention compared to the amount of prilocaine (2.5% w/w) in the comparative EMLA cream. Therefore, no clear and convincing unexpected benefit is seen to be present herein.

The Applicant further argues that Cassel solves a different problem than solved by the instant invention, and thus has a different motivation. In response it is respectfully submitted that the problem solved by Cassel is irrelevant. The motivation to combine need not be Applicant's motivation to invent. *In re Dillion*, 16 2d 1897 (Fed. Cir. 1990). The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

The Applicant further argues there is not a reasonable expectation of success in combining the lidocaine, prilocaine, and tetracaine, and that there were not a "finite number of identified, predictable solutions." The Examiner respectfully disagrees. Cassel clearly teaches that anesthetics with different pharmacodynamics and pharmocokinetics may be combined to improve the effectiveness and tolerance of the topical formulation (see page 3, section [0030]), wherein preferred anesthetics include

lidocaine, prilocaine, and tetracaine (see page 2, section [0028]). Further, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980). The combination of three topical anesthetics is expected to produce a composition with at least an additive anesthetic effect. Thus, the motivation to combine the different anesthetic compositions to form a third more effective composition flows logically from the art. Cassel also clearly teaches preferred combination of lidocaine and prilocaine and another of lidocaine and tetracaine. In looking to combine the anesthetics, the ordinary artisan would first look to the preferred embodiments to determine the anesthetics to combine.

Applicant argues that Cassel teaches away from the solution offered by the Applicant. It is respectfully submitted that Cassel does not teach away from Applicant's solution because it does not discredit, discourage, or dissuade the ordinary skilled artisan from formulating the instantly claimed composition. The teaching of the prior art is not limited to its preferred embodiments. The disclosed examples and preferred embodiments taught by Cassel do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971).

Applicant argues that Samuels solves a different problem and that the composition of the instant invention is not for the same purpose. As stated above, Applicant's reasons for inventing the composition need not be the same motivation gleaned from the prior art to combine the anesthetic compositions.

Applicant further argues that in teaching a vasodilator to lengthen the effective anesthetic time, Samuels teaches away from the combination of a third anesthetic. The Examiner respectfully disagrees. The combination of the different anesthetic compositions to form a third more effective composition flows logically from the art. Samuel's teaching of the vasodilator increasing the effective length of the anesthetic time provides motivation for adding a vasodilator to the composition, but does not teach away from what is logically present in the art.

Applicant argues that Lutz et al. requires a neutral or carboxylic acid-based active ingredient while the compositions of the instant invention do not, and that Lutz et al. is non-analogous art. The Examiner respectfully disagrees. Lutz et al. is relied upon as a secondary reference to demonstrate DMSO and N-methyl pyrrolidone are conventionally used as solvents in topical compositions because of their skin-tolerated penetration enhancing properties. Thus, it would be obvious to include DMSO and N-methyl pyrrolidone in topical formulations such as those taught by Cassel to enhance the skin penetration of the formulation.

Applicant argues that Santana et al. do not teach mucopolysaccharides but is limited to hyaluronidases. It is respectfully submitted that claim 17 requires mucopolysaccharides **or** hyaluronidases, and thus the teaching of hyaluronidases by Santana et al. is sufficient.

Applicant further argues that Santana et al. non-analogous art. The Examiner respectfully disagrees. Santana et al. is relied upon as a secondary reference to demonstrate hyaluronidases are conventionally used as diffusion factors (spreading

agents) in topical compositions because of their ability to increase penetration of the composition through the skin. Thus, it would be obvious to include hyaluronidases in topical formulations such as those taught by Cassel to enhance the skin penetration of the formulation.

Lastly, Applicant has alleged that the Examiner has taken "official notice" of the basic knowledge or common sense of a person of ordinary skill in the art. The Examiner respectfully disagrees. Official notice has not been taken. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 U.S.P.Q. 223, 235 (C.C.P.A. 1955).

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejections are maintained, and the instant claims are still considered properly rejected under 35 USC 103(a).

MAINTAINED REJECTIONS

6. The following rejections have been maintained from the previous Office Action dated 4/16/2008:

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-5, 7-12, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassel (US 2002/0128285).

The instant claims are directed to compositions for topical administration comprising therapeutically safe and effective amounts of lidocaine, prilocaine, and tetracaine or pharmaceutically acceptable salts thereof.

Cassel teaches topical delivery of a local anesthetic in a pharmaceutically acceptable topical drug formulation to an exterior surface of a surgically closed wound (see abstract and page 2, section [0025]). Cassel further teaches that the preferred local anesthetics include lidocaine, prilocaine, and tetracaine (see page 2, section [0028]) and that the local anesthetics may be combined in a pharmaceutically acceptable topical formulation, with a preferred combination containing lidocaine and prilocaine, and another containing lidocaine and tetracaine (see page 3, section [0030]). Cassel also teaches lidocaine and prilocaine as a eutectic mixture as claimed in the instant claim 3, wherein lidocaine is present in 1 to 40% by weight and prilocaine is present in 0.5 to 40% by weight, which overlaps or encompasses the ranges as claimed

for these components in the instant claims 4-5, and 25 (see page 4, section [0057]). Cassel also teaches that the preferred amounts for the lidocaine and tetracaine composition are lidocaine in 1 to 40% by weight and tetracaine in 0.5 to 40% by weight, which overlaps or encompasses the ranges as claimed for these components in the instant claims 4-5, 7, and 25 (see page 4, section [0058]). Cassel teaches that these compositions comprise carriers systems including buffered solutions (meaning the formulation contains water) or other art-known carriers, and that the any pharmaceutically acceptable excipient is acceptable, wherein the compositions are in the form of a gel, cream, or ointment as claimed in the instant claims 2, 8, and 24 (see page 3, section [0038] and page 4, section [0055], and page 5, section [0061]). Cassel teaches that penetration enhancers may be used in the formulations, and include N-methyl pyrrolidone as claimed in the instant claims 9-12, and 25 (see page 5, section [0065]). Cassel further teaches methods of using the compositions comprising topically applying the compositions to the exterior surface of a wound as claimed in the instant claim 26 **as best understood** (see page 5, Example I, and claim 1 for example).

Cassel does not explicitly teach a composition comprising a combination of lidocaine, prilocaine, and tetracaine. Cassel also does not explicitly teach compositions comprising the amounts of the components (i.e. anesthetics and methyl pyrrolidone) as claimed in the instant claims 4-5, 7, 11-12, and 25.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention, to combine the lidocaine/prilocaine composition with the lidocaine/tetracaine composition as taught by Cassel, to form a third composition

comprising all three anesthetic agents. One of ordinary skill in the art would have been motivated to do so because both prior art compositions have utility as topical anesthetic compositions, and the combination of the compositions is claimed to have utility as a topical anesthetic composition. It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose (See *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980)).

Furthermore, while the references do not explicitly teach the claimed amounts of anesthetic agents or methyl pyrrolidone, the determination of optimal or workable amount of these components by routine experimentation is obvious absent showing of criticality of the claimed amounts. One having ordinary skill in the art would have been motivated to optimize the amounts of the herein claimed anesthetics in order to obtain a composition with the desired anesthetic properties and desired skin penetrating effect. Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

9. Claims 1-5, 7-9, 19-20, 22, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuels et al. (US 2002/0006435 A1).

Samuels et al. teaches compositions for topical application comprising a therapeutically effective amount of topical anesthetic and a pharmaceutically carrier, and methods of administering the composition to a mammal (see abstract). Samuels et al. teaches that the compositions comprise 0.5 to 20% by weight of anesthetic agents, (see page 1, section [0015]), that preferred agents include lidocaine, prilocaine, and

tetracaine, and that preferably the anesthetic is eutectic mixture of anesthetics (see page 2-3, section [0035]). In a specific embodiments, Samuels et al. teaches a eutectic mixture of 3.5 % by weight lidocaine, 2.5% by weight prilocaine, and 1.5% by weight dibucaine (see page 3, section [0039], and page 8, Example 4), a eutectic mixture of 2.5% by weight lidocaine and 2.5% by weight prilocaine also comprising water as claimed in the instant claims 2-3 (see page 3, sections [0040]-[0041] and page 8, Example 5), and a mixture 12% by weight lidocaine and 12% by weight tetracaine hydrochloride (see page 9, Example 6). Samuels et al. further teaches that the compositions may be formulated as creams, lotions solutions, gels or sprays, and contains carriers such as emollients, emulsifiers, thickening agents, surfactants, etc. as claimed in the instant claims 8-9, and 24 (see page 4, section [0056]). Samuels et al. teaches that thickeners include gelling agents such as carbopol (carbomer), and that gums such as guar gum may also be incorporated into the composition as claimed in the instant claims 19-20 and 25 (see page 4, section [0060] and page 7, section [0100]. Samuels et al. further teaches that the compositions may comprise 0.5 to 2% by weight surfactant, and include nonionic surfactant such as polysorbate 20 (Tween 20), and polysorbate 80 (Tween 80) as claimed in the instant claims 9, 2, and 25 (see page 5, sections [0070] and [0073]). Samuels et al. also teaches methods of administering the composition comprising contacting the skin with said composition as claimed in the instant claim 26 **as best understood** (see page 7, sections [0108]-[0110]).

Samuels et al. does not explicitly teach a composition comprising a combination of lidocaine, prilocaine, and tetracaine. Samuels et al. also does not explicitly teach

compositions comprising the amounts of the components (i.e. anesthetics and methyl pyrrolidone) as claimed in the instant claims 4-5, 7, 19-20 and 25.

However, it would have been obvious to one of ordinary skill in the art at the time of the invention, to combine the lidocaine/prilocaine composition with the lidocaine/ tetracaine composition as taught by Samuels et al., to form a third composition comprising all three anesthetic agents. One of ordinary skill in the art would have been motivated to do so because both prior art compositions have utility as topical anesthetic compositions, and the combination of the compositions is claimed to have utility as a topical anesthetic composition. It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose (See *In re Kerkhoven*, 626 F.2d 846, 205, U.S.P.Q. 1069 (C.C.P.A. 1980)).

Furthermore, while the references do not explicitly teach the claimed amounts of anesthetic agents or viscosity increasing agent (thickener), the determination of optimal or workable amount of these components by routine experimentation is obvious absent showing of criticality of the claimed amounts. One having ordinary skill in the art would have been motivated to do this in order to obtain a composition with the desired anesthetic properties and viscosity. Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

10. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassel (US 2002/0128285) as applied to claims 1-5, 7-12, 24, and 26 above, and further in view of Lutz et al. (US 5,750,139).

Cassel is described above as applied to claims 1-5, 7-12, 24, and 26.

Cassel does not teach dimethyl sulfoxide, nor the amount present in the composition, as a penetration enhancer as claimed in the instant claims 14-15. Lutz et al. teaches that suitable solvents having penetration-enhancing properties are skin-tolerated penetration enhancers such as dimethyl sulfoxide (DMSO) or N-methylpyrrolidone (see column 8, lines 44-49).

It would have been obvious to one of ordinary skill in the art at the time of the invention, to substitute DMSO for N-methylpyrrolidone in the compositions taught and made obvious by Cassel. One of ordinary skill in the art would have been motivated to do because both DMSO and methyl pyrrolidone are art-recognized penetration enhancers as taught by Lutz et al. Furthermore, the determination of optimal or workable amount of DMSO by routine experimentation is obvious absent showing of criticality of the claimed amount. One having ordinary skill in the art would have been motivated to optimize the amount of DMSO in order to obtain a composition with the desired skin-penetrating effects. Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cassel (US 2002/0128285) as applied to claims 1-5, 7-12, 24, and 26 above, and further in view of Santana et al. (US 2003/0103955 A1).

Cassel is described above as applied to claims 1-5, 7-12, 24, and 26.

Cassel does not teach hyaluronidases or derivatives of mucopolysaccharides as a spreading agent in the compositions as claimed in the instant claim 17.

Santana et al. teaches topical compositions comprising diclofenac, papain, hyaluronidase, and vitamin E (see abstract). Santana et al. further teaches that the use of hyalurodinase as a diffusion factor (spreading agent) is known, and is compositions comprising the hyalurodinase have a high rate of penetration through the skin (see page 1, section [0012] and page 2, section [0016]).

It has been held that the selection of a known material based on its suitability for its intended use supported a *prima facia* obviousness determination in *Sinclair & Carroll Co. V. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the compositions taught or made obvious by Cassel by adding the spreading agent hyalurodinase as taught by Santana et al.

One of ordinary skill in the art would have a reasonable expectation of success in combining the above recited components, since it has been reasoned that reading a list and selecting a known compound to meet known requirements in no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle. *Sinclair & Carroll Co.*, 325 U.S. at 335, 65 USPQ at 301. Since all elements of the instant claims are taught in the cited references to be employed in topical compositions, combining the components for their intended use would have been *prima facia* obvious.

NEW REJECTIONS

12. In light of Applicant's amendments to claim 26, the following rejection has been modified from the original rejection of this claim under 35 U.S.C. 112, 2nd paragraph:

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 is unclear in that it claims a method of use of a composition comprising lidocaine, prilocaine, and tetracaine but does not indicate the use (i.e. for eliciting an anesthetic effect). Therefore, it is unclear what method Applicant intends to claim. Accordingly, the metes and bounds of the claim cannot be ascertained by one of ordinary skill in the art.

For examination purposes, and in the interest of compact prosecution, the claim will be interpreted as method of using said composition for the eliciting an anesthetic effect comprising applying the composition topically.

Allowable Subject Matter

14. Claim 25 is allowable over the prior art.

Conclusion

Claim 25 is allowable over the prior art. The remaining claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1617

/JENNIFER M KIM/

Primary Examiner, Art Unit 1617